K134013

510(k) Summary

APR 2 4 2014

Lyphochek Allergen sIgE Control

1.0 **Submitter**

Bio-Rad Laboratories
9500 Jeronimo Road,
Irvine, California 92618-2017
Telephone: (949) 598-1200
Fax: (949) 598-1557

Contact Person

Suzanne Parsons
Regulatory Affairs Manager
Telephone: (949) 598-1467

Date of Summary Preparation

Dec 27th, 2013

2.0 **Device Identification**

Product Trade Name:	Lyphochek Allergen sIgE Control ▪ Lyphochek Allergen sIgE Control, Negative ▪ Lyphochek Allergen sIgE Control, Panel A
Common Name:	Multi-Analyte Controls, All Kinds (Assayed)
Classifications:	Class I, Reserved
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

3.0 **Device to Which Substantial Equivalence is Claimed**

Baseline Allergen Controls – Inhalants Controls
Ventrex Laboratories
Predicate 510(k) Number: K832218

4.0 **Description of Device**

Lyphochek Allergen sIgE Control is prepared from human serum source material with added chemicals, stabilizers, and preservatives.

Each human donor unit used to manufacture this control was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2.

5.0 Value Assignment

The mean values and the corresponding ±3SD ranges printed in this insert were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications.

6.0 Intended Use

Lyphochek Allergen sIgE Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

7.0 Comparison of the new device with the Predicate Device

Lyphochek Allergen sIgE Control claims substantial equivalence to Baseline Allergen Controls – Inhalants Controls (*K832218*). Table 1 (below) contains comparison information of similarities and differences between the new and predicate device to which substantial equivalence is claimed.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Lyphochek Allergen sIgE Control *(New Device)*	Baseline Allergen Controls – Inhalants Controls (*Predicate Device, K832218*)
	Similarities	
Intended Use	Lyphochek Allergy Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.	Baseline Allergen Controls are human serum based system for use in evaluating the accuracy and precision of allergen specific IgE testing procedures, using either the radioallergosorbent or the enzyme immunoassay method.
Matrix	Human Serum	Human Serum
Preservatives	Contains preservatives	Contains preservatives
Storage unopened (Shelf life)	2-8 °C until expiration date	2-8 °C until expiration date
Levels	Lyphochek Allergen sIgE Control, Negative Lyphochek Allergen sIgE Control, Panel A	Baseline Allergen Control-Negative Baseline Allergen Control-Inhalants
	Differences	
Form	Lyophilized	Liquid
Open vial Stability	28 days at 2 to 8°C	No claims made
Fill Volume	2 mL	1 mL
Allergens	*Contains :* • D1: House dust mite (Dermatophagoides pteronyssinus) • D2: House dust mite (Dermatophagoides farinae) • E1: Cat dander (*Felis domesticus*) • E3: Horse dander (*Equus caballus*) • E5: Dog dander (*Canis familiaris*) • F13:Peanut (*Arachis hypogaea*) • G2: Bermuda grass (*Cynodon dactylon*) • G3: Orchard Grass (*Dactylis glomerata*) • G6: Timothy grass (*Phleum pratense*) • M3: Mold (Aspergillus fumigatus) • M6: Mold (Alternaria Tenuis)	*Contains :* • G1: Sweet Vernal Grass • G2: Bermuda grass • G3: Orchard Grass • G4: Meadow Fescue • G5: Perennial Rye Grass • G6: Timothy Grass • G7: Common Reed • G8: Kentucky Blue Grass • G9: Red Top (Bent Grass) • G10: Johnson Grass • W16: True (Rough) Marsh Elder • W17: Kochia (Firebrush) • W22: Careless Weed • W23: Yellow Dock • T1: Maple (Box Elder) • T2: Alder • T3:Birch • T4: Hazelnut

	• F1: Egg white (*Gallus spp.*) • F2: Cow's milk (*Bos. spp.*)	• T3: Birch (*Betula*) • W6: Mugwort (*Artemisia vulgaris*)	• G11: Brown Grass • G12: Cultivated Rye • G13: Velvet Grass • G14: Cultivated Oat Pollen • G15: Cultivated Wheat Pollen • G16: Meadow Foxtail • G17: Bahia Grass • W1: Common Ragweed • W2: Western Ragweed • W3: Giant Ragweed • W4: False Ragweed • W5: Wormwood • W6: Mugwort (common) • W7: Oxeye Daisy • W8: Dandelion • W9: English Plantain • W10: Lamb's Quarter • W11: Russian Thistle • W12: Goldenrod	• T5: Beech • T6: Mountain Cedar • T7: Oak • T8: Elm • T9: Olive Tree • T11: Sycamore • T12: Willow • T14: Cottonwood • T16: White Pine • T20: Mesquite • T21: Pecan Tree • E1: Cat Epithelium • E2: Dog Epithelium • E3: Horse Dander • E4: Cow Dander • H1: House dust (Greer) • H2: House dust (Hollister-Stier) • D2: Dermatophagoides farinae • I6: Cockroach
	Does not Contain: • G1: Sweet Vernal Grass • G4: Meadow Fescue • G5: Perennial Rye Grass • G7: Common Reed • G8: Kentucky Blue Grass • G9: Red Top (Bent Grass) • G10: Johnson Grass • G11: Brown Grass • G12: Cultivated Rye • G13: Velvet Grass • G14: Cultivated Oat Pollen • G15: Cultivated Wheat Pollen • G16: Meadow Foxtail • G17: Bahia Grass • W1: Common Ragweed • W2: Western Ragweed • W3: Giant Ragweed • W4: False Ragweed • W5: Wormwood • W7: Oxeye Daisy	• W8: Dandelion • W9: English Plantain • W10: Lamb's Quarter • W11: Russian Thistle • W12: Goldenrod • W16: True (Rough) Marsh Elder • W17: Kochia (Firebrush) • W22: Careless Weed • W23: Yellow Dock • T1: Maple (Box Elder) • T2: Alder • T4: Hazelnut • T5: Beech • T6: Mountain Cedar • T7: Oak • T8: Elm • T9: Olive Tree • T11: Sycamore • T12: Willow • T14: Cottonwood • T16: White Pine • T20: Mesquite • T21: Pecan Tree • E2: Dog Epithelium • E4: Cow Dander • H1: House dust (Greer) • H2: House dust (Hollister-Stier) • I6: Cockroach	**Does not Contain:** • D1: House dust mite • E5: Dog dander • F1: Egg white • F2: Cow's milk • F13:Peanut • M3: Mold • M6: Mold	

8.0 Statement of Supporting Data

Real time stability studies were performed to establish open vial stability. Accelerated stability studies were performed for establishing the shelf life stability. The stabilities for Lyphochek Allergen sIgE Control are as follows

Open vial Stability: 28 days at 2 to 8°C
Shelf Life Stability: 37 Months at 2 °C to 8 °C

9.0 Conclusion

Based on the performance characteristics indicated above, Lyphochek Allergen sIgE Control is substantially equivalent to the predicate device (K832218).

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

BIO-RAD LABORATORIES
C/O SUZANNE S. PARSONS
REGULATORY AFFAIRS MANAGER
9500 JERONIMO ROAD
IRVINE CA 92618

April 24, 2014

Re: K134013
Trade/Device Name: Lyphocheck Allergen sIgE Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I
Product Code: JJY
Dated: January 29, 2014
Received: January 30, 2014

Dear Ms. Parsons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Elizabeth A. Stafford -S

for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K134013

Device Name
Lyphochek Allergen sIgE Control, Negative/Panel A

Indications for Use *(Describe)*

Lyphochek Allergen sIgE Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth A. Stafford -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."